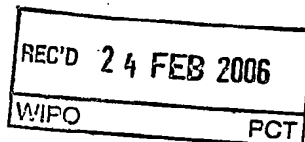


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2005/050417

International filing date (day/month/year)
01.02.2005

Priority date (day/month/year)
04.02.2004

International Patent Classification (IPC) or both national classification and IPC
G06K9/00, A61B5/02

Applicant
KONINKLIJKE PHILIPS ELECTRONICS, N.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2005/050417

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2005/050417

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-20
	No: Claims	
Inventive step (IS)	Yes: Claims	1-20
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Regarding Item V

- 1 The application relates to the field of biomedical signal processing. The problem to be solved is to automate the detection of artifacts among monitored signals (desc. p. 1, par. 3).
- 2 This problem is solved by the solution (S) consisting of the following common steps:
(Sc1) selecting pairs of correlated signals for each clinical condition (desc. p. 5, l. 15-23; fig. 21, step 3);
(Sc2) determining for each pair and clinical condition significance levels (also called "range of probability" in the description) that the null hypothesis of having no artifact is true (p. 4, l. 23 - p. 5, l. 14, 21-25; p. 7, l. 20-26; fig. 21, step 4);
(Sc3) calculating for each pair of observed signals and each clinical condition a p-value probability that the null hypothesis is true (p. 7, l. 6-26; p. 5, l. 23-25);

and of the following two alternative (Sa, Sb) sets of steps :

(Sa4) weighting these p-value according to their cumulative distribution and the significance levels for the given clinical condition (p. 7, l. 27-28; p. 5, l. 25-29; fig. 2, step 25)
(Sa5) obtaining the probability of having an artifact in a given signal under a given condition as the difference between one and the sum of the weighted p-values for the given signal (p. 7, l. 28-30; p. 6, equation (3)) and for the given condition (p. 6., l. 6; p.

(Sb4) determining that an artifact may exist in a signal if the null-hypothesis is rejected for any pair of observed signal (and clinical condition - this is unclear?) (p. 8, l. 20-22; Fig. 3)
- 3 Reference is made to the following documents:
D1 : ZONG W ET AL: "Reduction of false blood pressure alarms by use of electrocardiogram blood pressure relationships" COMPUTERS IN

CARDIOLOGY, 1999 HANNOVER, GERMANY 26-29 SEPT. 1999,
PISCATAWAY, NJ, USA, IEEE, US, 26 September 1999 (1999-09-26), pages
305-308, XP010367052 ISBN: 0-7803-5614-4

D2 : TSIEN C L ET AL: "MULTIPLE SIGNAL INTEGRATION BY DECISION TREE
INDUCTION TO DETECT ARTIFACTS IN THE NEONATAL INTENSIVE CARE
UNIT" ARTIFICIAL INTELLIGENCE IN MEDICINE, ELSEVIER, vol. 19, no. 3,
July 2000 (2000-07), pages 189-202, XP008059375 ISSN: 0933-3657

D3 : US 5 339 822 A (TAYLOR ET AL) 23 August 1994 (1994-08-23)

D4: Richard O. Duda et al, Pattern Classification, Wiley, New York, 2001, p 628-
630, XP2367999.

4 The subject-matter of independent claims 1, 13 and 20 is not considered to involve
an inventive step under **Article 33(3) PCT**.

4.1 Zong (resp. Tsien) discloses in document D1 (abstract; p. 307, l. col., par. 3)
(resp. in D2, abstract, p. 190, l. 10-12, 37-40; p. 198, l. 4-7; fig. 4, tables 1-3) a
method for monitoring patients by detecting artifacts by the pairwise integration
of different signal types, thus a method based on the assumption that these
signals are correlated.

4.2 The subject-matter of claim 1 differs from the methods of Zong or of Tsien by
the addition of the following feature :
(A) statistical hypothesis testing about pairs of signals.

4.3 However hypothesis testing is not only contained in most (if not all) statistics
handbooks, but is normally part of the training of engineers and scientists, e.g.
see the standard pattern recognition handbook D3, which discloses in an
appendix on p. 628-630 a reminder on testing a null hypothesis. Hence this
additional feature does not involve any skill or ability beyond that to be expected
of the person skilled in the art.

4.4 Hence the subject-matter of claim 1, having regard to the state of the art, is

obvious to the skilled person.

- 4.5 As the subject-matter of claim 13 is worded in terms of the apparatus corresponding to the method of claim 1, what has been said of claim 1 applies likewise to claim 13. The same applies also to claim 20.
- 5 The subject-matter of dependent claims 2-5, 14-15 relates to trivial features of computing or of biomedical engineering so that it does not add anything inventive to the subject-matter of independent claims 1 and 13.
5. As claim 6 (resp. 16) includes the features of claim 1 (resp. 13), it is considered dependent on claim 1 (resp. 13). It is also considered as not adding anything inventive.
- 5.1 The subject-matter of claims 6, 11 and 16 has the following additional features:
(B) calculating a cross-probability for each pair of signals
(C) calculating a confidence level for each cross-probability
(D) summing for a given signal all the cross-probabilities.
- 5.2 Each of these individual features taken by itself is known (and moreover feature (C) is not linked to the other features in these claims). As it is known from the most basic theory of probability that the sum of the probabilities for all possible events is one, it is trivial summing these probabilities to obtain by subtracting from one an artifact probability (this essential feature is missing from claim 6 and 16). Hence the subject-matter of claim 6 or 16 consists merely in the association, without overcoming any "technical" obstacle, of known or trivial features functioning in their normal way and not producing any non-obvious working inter-relationship, and functioning without any surprising effect.
- 5.3 It is remarked that the last feature of claim 11 (indication to operator) is trivial.

- 6 The subject-matter of dependent claims 7-10, 12, 14-15, 17-19 does not add anything inventive as it consists merely in the association, without overcoming any "technical" obstacle, of known, trivial or obvious features functioning in their normal way and not producing any non-obvious working inter-relationship without any surprising effect.

Regarding Item VIII

- 1 The Claims do not define the matter for which protection is sought (see item V.2 above), **in violation of Article 6 PCT.**